

REMARKS

Claims 17, 18, and 19 are currently pending. Support for the amendment to claim 17 can be found in paragraph 0057 of the substitute specification (see also page 8, 2nd paragraph of the preliminary amendment filed at the time of filing the application).

Re-examination and reconsideration of the pending claims is respectfully requested.

Objections to the Specification

The Office Action objected to the specification because of a lack of description of Figures 9 and 10. Also, the Office Action noted that the specification did not indicate the parts of the application.

In response, Applicant is providing a substitute specification to address the above objections. Applicant believes the issues noted above are addressed by way of this amendment and believe that the amendments do not introduce any new matter into the subject application.

Double Patenting

The Office Action rejected claims 17-19 on the ground of nonstatutory obvious-type double patenting over claims 1 and 13 of U.S. Patent No. 6,371,980 in view of Bhatnagar, 5,958,428.

Applicant disagrees. However, to expedite prosecution of the subject application, applicant is submitting a terminal disclaimer herewith.

35 U.S.C. §103 - I

The Office Action rejects claims 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428, or in the alternative, over Alcime et al., 5,632,772 in view of Bhatnagar, 5,958,428, and further in view of Barone et al., 5,360,443.

Applicant disagrees. Generally, the present rejection does not establish *prima facie* obviousness under 35 U.S.C. §103 and M.P.E.P. §§2142-2143. The Office Action

bears the initial burden to establish and support *prima facie* obviousness. *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143 (CCPA 1976). To establish *prima facie* obviousness, three basic criteria must be met. M.P.E.P. § 2142. First, the Office Action must establish that the prior art references, alone or in combination, teach or suggest all the claim limitations. M.P.E.P. § 2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Second, the Office Action must show some suggestion or motivation, either in the prior art references or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the reference teachings so as to produce the claimed invention. M.P.E.P. § 2143.01; *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Third, the Examiner must establish that there is a reasonable expectation of success for the modifications. M.P.E.P. § 2142. Applicant respectfully submits that a *prima facie* case of obviousness has not been met because the Office Action's rejection in the above requirements.

First, applicant notes that Alcime teaches surface treatments to place substances on the coatings/liner of the Alcime device to improve the tissue response of the tissue adjacent to the device. For example, the use of drugs such as heparin, antiplatelet agents, antiplatelet-derived growth factors, antibiotics, steroids, lytic agents, etc. provide local drug therapy. (See Alcime col. 13, lines 53-62). Alcime also teaches the use of materials that encourage desirable growth of tissue. (See Alcime col. 13, lines 34-52; col. 3, lines 1-5; and the Abstract).

In addition, Barone teaches the use of various materials, but then teaches that the “[t]ube 160 can also be made of a bio-erodable, or degradable material, such as albumin or collagen or a collagen coated material. A tube 160 which is bio-erodable, would erode and dissolve, or degrade, over a period of time; however, it is believed that a layer of endothelium, or skin, will grow as the tube 160 erodes, the new layer of endothelium, or skin, providing a new, fluid impervious lining within aneurysm 151.” (Col. 6, line 55 through Col. 7, line 12).

The Office Action fails to state why one would veer from the teachings of Alcime or Barone to modify a polymer that is otherwise unsuitable to become suitable. In other words, applicant's claims recite a device that has a polymer material that is treated to make an inhospitable polymer material more hospitable for endothelial cell growth.

Secondly, Applicant notes that there is no motivation or suggestion, either in the cited art references or in the knowledge generally available to one of ordinary skill in the art, to combine the teachings to arrive at applicant's claim.

Applicant further points out that the Office Action bears the initial burden of factually establishing and supporting any *prima facie* conclusion of obviousness. *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143 (CCPA 1976); M.P.E.P. § 2142. If the Office Action does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* In the instant case, the Office Action has not pointed to any concrete evidence in the art which provides a suggestion or motivation to combine the cited references so as to produce the claimed invention. See *In re Zurko*, 258 F.3d 1379, 59 U.S.P.Q.2d 1693 (Fed. Cir. 2001) ([I]n a determination of patentability the Board cannot simply reach conclusions based on its understanding or experience - or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings).

For the several reasons discussed above, it is respectfully requested that the § 103(a) rejection of independent claims 17 and 19 be withdrawn and the claims be allowed.

35 U.S.C. §103 - II

The Office Action rejects claim 19 under 35 U.S.C. §103(a) as being unpatentable over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428 and further in view of Brown et al. 6,071,305(, or in the alternative, over Alcime et al., 5,632,772 in view of Bhatnagar, 5,958,428, and Barone et al., 5,360,443 and further in view of Brown et al. 6,071,305).

As noted above, the Office Action fails to establish a proper *prima facie* case. The addition of Brown et al. does nothing to remedy this defect. In view of the above, Applicant requests withdrawal of this rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **NFCSNZ00801**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,


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